

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Emmanuel Mastorakis

For : MEDICAL DEVICE AND LOCKING MECHANISM THEREFOR

Assistant Commissioner for Patents  
Box Patent Application  
Washington, D.C. 20231

Dear Sir:

PRELIMINARY AMENDMENT

Prior to examination please amend the above-identified application as follows:

In the Claims:

Amend claims 4, 5, 8, 10, 20, 21, 28, 30, 31, 33, 35-38, 45, 47, 48 and 56 to read as follows:

4. A locking mechanism as claimed in claim 1 in which the retainer part includes a flexible leg, the first formation being located on the leg, the connector part being adapted to flex the leg, on engagement with the retainer part, to move the first formation relative to the body part.
5. A locking mechanism as claimed in claim 4 in which the first formation and second formation comprise a lug and a recess, each being formed on or in one of the retainer part and the body part, and in which the retainer part includes two of said legs, the connector part being adapted to move the legs towards one another on engagement with the retainer part.
8. A locking mechanism as claimed in claim 4 in which each leg has an inner surface and an outer surface, the outer surface being longer than the inner surface.

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10. A locking mechanism as claimed in claim 1 in which the connector part includes a bore into which at least part of the retainer part is insertable.

14. A locking mechanism as claimed in claim 1 in which the retainer part is adapted to retain a hypodermic needle, the retainer part including an elongate bore passing therethrough, the bore being engageable with a cylindrical outer surface of a needle.

20. A locking mechanism as claimed in claim 17 in which each said leg includes a lug adapted for engagement with a recess formed in the body part, the movement of the connector part to engage the leg causing a reduction in the force of engagement between the lug and recess.

21. A locking mechanism as claimed in claim 17 in which the connector part includes a generally cylindrically bore, the bore being adapted to receive each said leg on engagement of the connector part therewith.

28. An assembly as claimed in claim 26 in which the needle retainer has a cylindrical body and has a bore formed therealong, the bore having an entrance thereto, the needle retainer being insertable into the neck portion to a position in which the entrance to the bore is located spaced at least partly along the neck portion from the open front end thereof to the shoulder.

30. An assembly as claimed in claim 28 in which the needle retainer and neck portion are circularly cylindrical, and in which an outer diameter of the needle retainer is substantially equal to an inner diameter of the neck portion.

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31. An assembly as claimed in claim 26 in which the fluid container is formed with an annular internal recess at the axial point at which the neck portion meets the shoulder portion thereof, and in which the needle retainer includes at least one projection adapted to engage with the recess for retaining the needle retainer in position in the fluid container.

33. An assembly as claimed in claim 26 in which a seal is provided on the needle retainer for sealing with the internal surface of the neck portion.

35. An assembly as claimed in claim 26 in which the needle has a sharp front end, and a rear end, the rear end being adjacent a rear end of a cylindrical body of the needle retainer.

36. An assembly as claimed in claim 26 which includes means for forcing fluid out of the container and along the needle.

37. A medical device including a needle assembly as claimed in claim 16.

38. A medical device including a locking mechanism as claimed in claim 1.

45. A medical device as claimed in claim 42 in which the syringe includes a barrel, a conical shoulder portion at a forward end of a main cylindrical part of the barrel and a neck portion in front of the shoulder portion, the said second formation of the locking mechanism being formed internally in the neck portion.

47. A medical device as claimed in claim 38 in which the retainer part is removably mounted on the body part of the device.

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48. A medical device as claimed in claim 47 in which the retainer part is removably mounted on the body part of the device, and which includes a hub part for releasably sealably retaining the retainer part on the barrel of the syringe.

56. A device as claimed in claim 53 in which the plunger has a stem with an X-shaped section and the barrel is formed with a groove allowing axial movement but preventing rotation of the plunger stem.

Cancel claims 50-52.

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REMARKS

Claims 4, 5, 8, 10, 20, 21, 28, 30, 31, 33, 35-38, 45, 47, 48 and 56 have been amended to remove multiple dependency. Claims 50-52 have been cancelled. Claims 1-49 and 53-56 will be pending in the application upon entry of this Preliminary Amendment.

A marked-up version of the claims is attached hereto, wherein deleted matter has been bracketed and added matter is underlined.

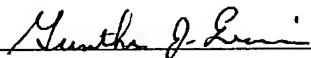
In view of the above amendments, it is respectfully submitted that the application is in condition for allowance and notice of same is earnestly solicited.

Respectfully submitted,

EMMANUEL MASTORAKIS

By: Price, Heneveld, Cooper,  
DeWitt & Litton

February 21, 2002  
Date

  
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claims 4, 5, 8, 10, 20, 21, 28, 30, 31, 33, 35-38, 45, 47, 48 and 56 have been amended as follows:

4. A locking mechanism as claimed in [any preceding] claim 1 in which the retainer part includes a flexible leg, the first formation being located on the leg, the connector part being adapted to flex the leg, on engagement with the retainer part, to move the first formation relative to the body part.
5. A locking mechanism as claimed in claim 4 [when dependent upon claim 3] in which the first formation and second formation comprise a lug and a recess, each being formed on or in one of the retainer part and the body part, and in which the retainer part includes two of said legs, the connector part being adapted to move the legs towards one another on engagement with the retainer part.
8. A locking mechanism as claimed in [any one of] claim[s] 4 [to 7] in which each leg has an inner surface and an outer surface, the outer surface being longer than the inner surface.
10. A locking mechanism as claimed in [any preceding] claim 1 in which the connector part includes a bore into which at least part of the retainer part is insertable.
14. A locking mechanism as claimed in [any preceding] claim 1 in which the retainer part is adapted to retain a hypodermic needle, the retainer part including an elongate bore passing therethrough, the bore being engageable with a cylindrical outer surface of a needle.

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20. A locking mechanism as claimed in [any one of] claim[s] 17 [to 19] in which each said leg includes a lug adapted for engagement with a recess formed in the body part, the movement of the connector part to engage the leg causing a reduction in the force of engagement between the lug and recess.

21. A locking mechanism as claimed in [any one of] claim[s] 17 [to 20] in which the connector part includes a generally cylindrically bore, the bore being adapted to receive each said leg on engagement of the connector part therewith.

28. An assembly as claimed in claim 26 [or claim 27] in which the needle retainer has a cylindrical body and has a bore formed therealong, the bore having an entrance thereto, the needle retainer being insertable into the neck portion to a position in which the entrance to the bore is located spaced at least partly along the neck portion from the open front end thereof to the shoulder.

30. An assembly as claimed in [any one of] claim[s] 28 [to 29] in which the needle retainer and neck portion are circularly cylindrical, and in which an outer diameter of the needle retainer is substantially equal to an inner diameter of the neck portion.

31. An assembly as claimed in [any one of] claim[s] 26 [to 30] in which the fluid container is formed with an annular internal recess at the axial point at which the neck portion meets the shoulder portion thereof, and in which the needle retainer includes at least one projection adapted to engage with the recess for retaining the needle retainer in position in the fluid container.

33. An assembly as claimed in [any one of] claim[s] 26 [to 32] in which a seal is provided on the needle retainer for sealing with the internal surface of the neck portion.

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35. An assembly as claimed in [any one of] claim[s] 26 [to 34] in which the needle has a sharp front end, and a rear end, the rear end being adjacent a rear end of a cylindrical body of the needle retainer.

36. An assembly as claimed in [any one of] claim[s] 26 [to 35] which includes means for forcing fluid out of the container and along the needle.

37. A medical device including a needle assembly as claimed in [any one of] claim[s] 16 [to 36].

38. A medical device including a locking mechanism as claimed in [any one of] claim[s] 1 [to 25].

45. A medical device as claimed in claim 42 [or 43 or 44] in which the syringe includes a barrel, a conical shoulder portion at a forward end of a main cylindrical part of the barrel and a neck portion in front of the shoulder portion, the said second formation of the locking mechanism being formed internally in the neck portion.

47. A medical device as claimed in [any one of] claim[s] 38 [to 45] in which the retainer part is removably mounted on the body part of the device.

48. A medical device as claimed in claim 47 [when dependent upon claim 25] in which the retainer part is removably mounted on the body part of the device, and which includes a hub part for releasably sealably retaining the retainer part on the barrel of the syringe.

56. A device as claimed in [any one of] claim[s] 53 [to 55] in which the plunger has a stem with an X-shaped section and the barrel is formed with a groove allowing axial movement but preventing rotation of the plunger stem.



03/07 '02 12:10

PRORISCO SA 10/069,688 10/069,688  
Atty. Docket No. KIL01 P-424 #3.

Applicant : Emmanuel Mastorakis  
Serial No. : 10/069,688  
Filed : February 21, 2002  
Confirmation No. :  
For :

**MEDICAL DEVICE AND LOCKING MECHANISM THEREFOR****VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY  
STATUS (37 CFR §1.9(f) and 1.27(c)) - SMALL BUSINESS CONCERN**

I hereby declare that I am:

- ( ) the owner of the small business concern identified below;  
(X) an official of the small business concern empowered to act on behalf of the concern identified below.

NAME OF CONCERN: Nicodol S.A.  
ADDRESS OF CONCERN: 10 Rue St. Pierre, CP-447 - 1701, Fribourg, Switzerland

I hereby declare that the above-identified small business concern qualifies as a small business; concern as defined in 13 CFR §121.3-18, and reproduced in 37 CFR §1.9(d), for purposes of paying reduced fees under sections 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled **MEDICAL DEVICE AND LOCKING MECHANISM THEREFOR**, by inventor Emmanuel Mastorakis described in:

- ( ) the specification filed herewith.  
(X) application Serial No. 10/069,688, filed February 21, 2002.  
( ) Patent No. \_\_\_\_\_, issued \_\_\_\_\_.

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below\* and no rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor under 37 CFR §1.9(c) or by any concern which would not qualify as a small business concern under 37 CFR §1.9(d) or a nonprofit organization under 37 CFR §1.9(e). \*NOTE: Separate Verified Statements are required from each named person, concern or organization having rights to the invention affecting to their status as small entities (37 CFR §1.27).

NAME \_\_\_\_\_  
ADDRESS \_\_\_\_\_  
( ) INDIVIDUAL ( ) SMALL BUSINESS CONCERN ( ) NON-PROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR §1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this Verified Statement is directed.

NAME OF PERSON SIGNING Dr. Tania e Castro  
TITLE OF PERSON OTHER THAN OWNER Director  
ADDRESS OF PERSON SIGNING 10 Rue St. Pierre - 1701 Fribourg  
SIGNATURE [Signature] DATE 03/07/2002